sub-committee of the Drugs Consultative Committee (DCC) and as such has not commented on these combinations.

(e) Does not arise.

Marketing of Digestive Enzymes

2633. SHRI ASHOK NATH VERMA:
DR. (SHRIMATI) SAROJINI MAHISHI:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that digestive enzymes are being marketed in the country;

(b) what are the details of composition allowed for marketing;

(c) whether his Ministry considered the rationale for quantity, dosage form and combinations of each;

(d) if so, the details thereof;

(e) whether it is a fact that his Ministry have found a number of these products irrational, as far as the quantity, dosage form and combinations of other drugs are concerned;

(f) if so, the names of such compositions;

(g) what steps have been taken to ban these compositions; and

(h) by when the action would be taken and irrational compositions banned?

THE MINISTER OF STATE OF THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI RAFIQUE ALAM): (a) Yes, Sir.

(b) Details of enzyme preparations, licensed by the State Drug Controller, marketed in India, are given in the Statement-I. (*See* below).

(c) The sub-committee of experts of the Drugs Consultative Committee has reviewed and examined the enzyme preparations moving in the market.

(d) to (h) A statement-II is enclosed. (*See* below).

Statement I

Popular Enzyme Preparations

ALVIZYME ALEMBIC
Pancr atin 125mg, (having amylase activity not less than 750u. protease activity not less than 3000u. & lipase activity not less than 640 u.) simethicone 25 mg. tabs.

PARIZYM FORTE Infar
Lipase not less than 6000 fip u. protease not less than 350 fip u. amylase not less than 4000 fip u. cellulase to an activity of 2.5 w.u. cholic acid (as bile ext.) 30 mg; tabs.

BESTOZYME BIOLOGICAL-E
Alpha amylase (1:250) 320 mg, papain 60 mg, activated dimethicone 40mg; cap.

DIGEPLEX Rallis
Diastase (1:250) 20mg, pepsin 20 mg. vit. B-1 1mg, B-2 1mg, B-6 0.5 mg, dipantothenyalcohol 25mg, nicotinamide 10 mg, B-12 0.5 mg, per 10ml; liq. (Tabs. cont. diastase, vit. B-12 supplied. separate to be crushed and mised before intake)

DISPEPTAL Boehnnger-K
Pancreatin 150mg, veg. enzymes 33mg (equiv. to cellulases & hemicellulases activity of 6 Grassmann units), bile salts 25 mg, dragees.

DIZYTONE Unichem
Fungal diattase (1:75) 900 mg, vit. B-1 6 mg, B-2 5 mg, B-6 1.5 mg, B-12 5 mg niacinamide 48 mg, d-panthenol 5 mg. per 15 ml, syrup.

ENZYMES SYRUP IPCA
Fungal diastase (1.50) 500 mg, pepsin 15 mg, vit. B-1 2.5 mg, B-2 2.5 mg, nicotinamide 22.5 mg, d-panthenol 2.5 mg, B-6 1mg, methylpotysiox. 20 mg, per 5 ml.

VITAZYME East India
Fungal diastase (1:2000) 20 mg. vit. B-1 0 3 mg, B-2 0.5 mg, B-6 0.25 mg, nicotinamide 4 mg. per 5 ml. liq.

FESTAL HOECHST
Pancreatin 192 mg, bile constituents 25 mg, hemicellulase 50 mg, dragees.

LUPIZYME Lupin
Peoson (1:3000) 12.5 mg.
diastase (1:2000) 18.75 mg. vit B-12 mg.
B-2 1mg, B-6 1 5 mg, B-12 mcg.
d-panthenol 1 5 mg, nicotinamide 15 mg.
per 5 ml. syrup.

MERCHENZYME MERCK
Bromelains 750 u. pancreatin
400 mg, ox bile 30 mg, tabs.

MOLZYME FDC
Papain 60 mg, diastase (1:150)
3.75 mg, cumin oil 0 05 ml. ajowan
oil 0.015 ml, activated wood
charcoal 100 mg, simethicone 25 mg,
belladonna dry ext. 8 mg, tabs.

NEOPEPTINE RAPTAKOS
Alpha-amylase 200 mg. papain 100 mg.
Vit. B-1 5 mg. B-2 3 mg, B-6 1mg,
B-12 5 mcg, nicotiramide 25 mg,
simethicone 30 mg, caps.

NORMOZYME Uniloids
Fungal diastase 300 mg, papain
25 mg, methylpolysilox. 20 mg,
bile ext. 25 mg, caps.

PANZYNORM German Remedies
Pancreatin 100 mg, bile ext. 40 mg dry
stomach ext. 100 mg. (derived from
approx. 2 g. fresh stomach equivl to
20 mg. pepsin); tabs.

RALCRIZYME Rallis
Pancreatin 150 mg, bileext. 25 mg.
pepsin 5 mg. diastase(1:2000) 10 mg.
dimethyisiloxane 25 mg, drageés.

UNIENZYME Unichem
Fungal diastase (1:75) 200 mg, papain 30 mg,
simethicone 50 mg, nicotinamide 25 mg,
acephenolisatin 0 5 mg, dipherihydramin hcl
20 mg, activated charcoal 75 mg: tabs.

VIZYLAC Unichem
Lactobacilus sporogenes 40 millio spores, fungaldiastase (1:75) 250 mg, papain 20 mg,
methylpolysilox. 40 mg vit. B-1 2 mg, B-2 2.5
mg, B6 0.5 mg, nicotinamide 15 mg, folic
acid 75 mcg, d-panthenol 1 mg: caps.

Statement-II

Enzyme preparations moving in the market contain Amylase and Diastase (carbohydrate splitting enzyme); Lipase (fat splitting enzyme); Protease (protein splitting enzyme); Pancreatase (enzyme found in pancreas for digestion). They are promoted in digestive disorders such as indigestion and also in pancreatic insufficiency conditions such as cysticfibrosis, chronic pancreatitis, etc. Some of the preparations were found to contain enzymes which are active in acid pH and some in alkalin pH. Examination also revealed that some enzymes could act only in critical pH and may not be very stable. It was considered that the manufacturers of enzyme preparations must ensure that their preparations should be stable, ingredients present in the preparation should be compatible with each other and should be present in therapeutic doses in the formula.

The experts had opined that enzyme preparations containing non-enzyme ingredient such as intestinal sedatives (*e.g.* diphen hydramine) or laxatives or antispasmodics should be subjected to clinical trials. The experts have asked the manufacturers to prove the advantages of adding non-enzyme ingredients in enzyme preparations through controlled clinical trials.

Marketing of Central Activators

2634. SHRI P. N. SUKUL:
DR. (SHRIMATI) SAROJINI MAHISHI:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) what are the Central Activators being marketed in the country;

(b) when the permission for each was granted;

(c) whether it is a fact that Narmabrain, Encephabel and Pristam are being marketed in the country;

(d) whether it is also a fact that these products are irrational;

(e) what is the justification in allowing the marketing of each product;

(f) what is the composition of each and the price at which each is being sold;

(g) what are the details of side effects, centre-indication and dangerous effects of each product;

(h) whether it is a fact that the Ministry of Health and Family Welfare are proposing to withdraw these products; and

(i) if so, when and if not, the reasons therefor?